JUL - 9 2009

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is supplied in accordance with the requirements of the SMDA of 1990 and 21 CFR 807.92

The assigned 510(k) number is **K083130**.

Date: July 6, 2009

Submitted by: Wallac Oy – PerkinElmer Inc.
Mustionkatu 6
20750 Turku, Finland

Contact person:

Primary: Kay A. Taylor
Tele: 317-418-1735
Fax: 317-536-3064

Secondary: Raija Koskivaara
Tele: +358-2-2678 111
Fax: +358-2-2678 357

Trade Name: NeoBase Non-derivatized MSMS Kit

Common Name: NeoBase kit or Non-derivatized kit

Classification Name: Newborn screening test system for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry (21 CFR § 862.1055 /Product code NQL)

Predicate device(s): NeoGram Amino Acids and Acylcarnitines Tandem Mass Spectrometry Kit, K031878

Device description: The measurement of amino acids, succinylacetone, free carnitine, and acylcarnitines with the NeoBase assay involves extraction of dried blood spots from newborns with a solution containing stable-isotope labeled internal standards and analysis using a tandem mass spectrometry (MSMS) system. The response of each analyte relative to their

corresponding stable-isotope labeled internal standard is proportional to analyte concentration

Intended Use: The NeoBase Non-derivatized MSMS reagent kit is intended for the measurement and evaluation of amino acids, succinylacetone, free carnitine, and acylcarnitine concentrations from newborn heel prick blood samples dried on filter paper. Quantitative analysis of these analytes (Tabel 1) and their relationship with each other is intended to provide analyte concentration profiles that may aid in screening newborns for metabolic disorders.

Instruments:
- PerkinElmer MS2 Tandem Mass Spectrometer System and,
- PerkinElmer MS/MS Qmicro Screening System

Table 1. Analytes measured by the NeoBase Non-derivatized MSMS Kit.

ANALYTE NAME	ABBREVIATION
Amino acids	
Alanine	Ala
Arginine	Arg
Citrulline	Cit
Glycine	Gly
Leucine/Isoleucine/Hydroxyproline*	Leu/Ile/Pro-OH
Methionine	Met
Ornithine	Orn
Phenylalanine	Phe
Proline	Pro
Tyrosine	Tyr
Valine	Val
Carnitines	
Free carnitine	C0
Acetylcarnitine	C2
Propionylcarnitine	C3
Malonylcarnitine / 3-Hydroxy-butyrylcarnitine*	C3DC/C4OH
Butyrylcarnitine	C4
Methylmalonyl / 3-Hydroxy-isovalerylcarnitine*	C4DC/C5OH
Isovalerylcarnitine	C5
Tiglylcarnitine	C5:1
Glutarylcarnitine / 3-Hydroxy-hexanoylcarnitine*	C5DC/C6OH
Hexanoylcarnitine	C6
Adipylcarnitine	C6DC
Octanoylcarnitine	C8
Octenoylcarnitine	C8:1

Decanoylcarnitine	C10
Decenoylcarnitine	C10:1
Decadienoylcarnitine	C10:2
Dodecanoylcarnitine	C12
ANALYTE NAME	ABBREVIATION
Carnitines	
Dodecenoylcarnitine	C12:1
Tetradecanoylcarnitine (Myristoylcarnitine)	C14
Tetradecenoylcarnitine	C14:1
Tetradecadienoylcarnitine	C14:2
3-Hydroxy-tetradecanoylcarnitine	C14OH
Hexadecanoylcarnitine (palmitoylcarnitine)	C16
Hexadecenoylcarnitine	C16:1
3-Hydroxy-hexadecanoylcarnitine	C16OH
3-Hydroxy-hexadecenoylcarnitine	C16:1OH
Octadecanoylcarnitine (Stearoylcarnitine)	C18
Octadecenoylcarnitine (Oleylcarnitine)	C18:1
Octadecadienoylcarnitine (Linoleylcarnitine)	C18:2
3-Hydroxy-octadecanoylcarnitine	C18OH
3-Hydroxy-octadecenoylcarnitine	C18:1OH
Ketones	
Succinylacetone	SA

*Analytes in these rows are either isomers or isobars and cannot be distinguished in the tandem mass spectrometry experiment.

Device Comparison:

Table 5.1: Comparison of the NeoBase Non-derivatized MSMS and predicate device.

GENERAL CHARACTERISTICS		
Parameter	**NeoBase Non-derivatized MSMS kit**	**Predicate Device**
Intended Use	The NeoBase Non-derivatized MSMS reagent kit is intended for the measurement and evaluation of amino acids, succinylacetone, free carnitine, and acylcarnitine concentrations from newborn heel prick blood samples dried on filter paper. Quantitative analysis of these analytes (Table 1) and their relationship with each other is intended to provide analyte concentration profiles that may aid in screening newborns for metabolic disorders. [intended use employs a table to identify each analyte detected]	The NeoGram Amino Acids and Acylcarnitines Tandem Mass Spectrometry kit is intended for the measurement and evaluation of amino acids, free carnitine, and acylcarnitine concentrations from newborn heel prick blood samples dried on filter paper. Table 1 details the analytes measured by the kit Quantitative analysis of amino acids, free carnitine, and acylcarnitine and their relationship with each other is intended to provide analyte concentration profiles that may aid in screening newborns for one or more of several metabolic disorders. This kit is to be used for in vitro

		diagnostic use only, by trained, qualified laboratory personnel. [intended use employs a table to identify each analyte detected]
Disorders Screened	Amino-, organic-, and fatty acid metabolic disorders	Same
Analytes Measured	Amino acids, free carnitine, acylcarnitines, and succinylacetone	Amino acids, free carnitine, and acylcarnitines
Methodology	Microplate based tandem mass spectrometric assay	Same
Test Principle	Amino acids and carnitines in sample are measured by tandem mass spectrometry through analyte-specific mass transitions appropriate for each type of analyte. The extracted analytes are measured for set time periods and compared to the signal intensities produced by the corresponding isotope-labeled internal standards. The concentrations are determined by comparing the signal intensities of the known standards to the measured analytes.	Same
Quantitative Nature	Quantitative by internal standardization	Same
Sample Requirements	Newborn blood collected on Schleicher and Schuell 903 filter paper per NCCLS standards	Same
Throughput	Ninety-six tests per microtiter plate. Multiple plates can be analyzed	Same
Analysis Time	2 to 2.5 hours per plate.	Same
Controls	Controls are blood spots from processed human blood enriched with several amino acids, carnitines and succinylacetone.	Controls are blood spots from processed human blood enriched with several amino acids and carnitines.
Calibrators	Internal calibration using several isotopically labeled standards, included as dried material in vials. Internal standards must be reconstituted with extraction solution prior to their use.	Same
Assay format	Non-derivatized (analytes measured in their native forms)	Derivatized (analytes converted to butyl esters prior to being measured)

Analytes measured by the device

Table 5.2: Analytes measured by the NeoBase kit and their most common abbreviated names

ANALYTE NAME	ABBREVIATION
Amino acids	
Alanine	Ala
Arginine	Arg
Citrulline	Cit
Glycine	Gly

Leucine/Isoleucine/Hydroxyproline*	Leu/Ile/Pro-OH
Methionine	Met
Ornithine	Orn
Phenylalanine	Phe
Proline	Pro
Tyrosine	Tyr
Valine	Val
Carnitines	
Free carnitine	C0
Acetylcarnitine	C2
Propionylcarnitine	C3
Malonylcarnitine / 3-Hydroxy-butyrylcarnitine*	C3DC/C4OH
Butyrylcarnitine	C4
Methylmalonyl / 3-Hydroxy-isovalerylcarnitine*	C4DC/C5OH
Isovalerylcarnitine	C5
Tiglylcarnitine	C5:1
Glutarylcarnitine / 3-Hydroxy-hexanoylcarnitine*	C5DC/C6OH
Hexanoylcarnitine	C6
Adipylcarnitine	C6DC
Octanoylcarnitine	C8
Octenoylcarnitine	C8:1
Decanoylcarnitine	C10
Decenoylcarnitine	C10:1
Decadienoylcarnitine	C10:2
Dodecanoylcarnitine	C12
Dodecenoylcarnitine	C12:1

Table 5.2: Analytes measured by the NeoBase kit and their most common abbreviated names (continued)

Tetradecanoylcarnitine (Myristoylcarnitine)	C14
Tetradecenoylcarnitine	C14:1
Tetradecadienoylcarnitine	C14:2
3-Hydroxy-tetradecanoylcarnitine	C14OH
Hexadecanoylcarnitine (palmitoylcarnitine)	C16
Hexadecenoylcarnitine	C16:1
3-Hydroxy-hexadecanoylcarnitine	C16OH
3-Hydroxy-hexadecenoylcarnitine	C16:1OH
Octadecanoylcarnitine (Stearoylcarnitine)	C18
Octadecenoylcarnitine (Oleylcarnitine)	C18:1
Octadecadienoylcarnitine (Linoleylcarnitine)	C18:2
3-Hydroxy-octadecanoylcarnitine	C18OH
3-Hydroxy-octadecenoylcarnitine	C18:1OH
Ketones	
Succinylacetone	SA or SUAC

*Analytes in these rows are either isomers or isobars and cannot be distinguished in the tandem mass spectrometry experiment.

Substantial equivalency:

(1) Non-clinical

The NeoBase Non-derivatized MSMS kit was compared to the predicate NeoGram Amino Acids and Acylcarnitines Tandem Mass Spectrometry Kit, k031878. Both devices utilize tandem mass spectrometry to measure a panel of

amino acids and acylcarnitines from neonatal dried blood spots. The panel of analytes measured by both devices is the same with the main exception that the NeoBase kit also includes the measurement of succinylacetone (the primary marker for the screening of Tyrosinemia Type I). Analytically, both devices are also very similar with the exception that the NeoBase kit does not require the derivatization of the sample prior to measurement (Tables 5.1 and 5.2).

The established performance characteristics of the NeoBase kit were compared against the corresponding characteristics reported in the predicate device product insert. A summary of the performance characteristics is presented in Tables 5.3 to 5.6. Both kits provide equivalent precision and recoveries and both devices have measurable ranges that cover all clinically significant ranges. Therefore, both kits provide performance levels that are adequate for their intended use.

Precision

Table 5.3: Averaged Total imprecision for amino acids. Data shown are average Total imprecision coefficients of variation (%CV) for both assays.

Assay	ALA	ARG	CIT	GLY	LEU	MET	ORN	PHE	TYR	VAL
NeoBase	8	7	8	9	7	7	8	8	7	8
Predicate	9	10	8	8	9	9	9	8	8	14

Table 5.4: Averaged Total imprecision for carnitine and acylcarnitines. Data shown are average Total imprecision coefficients of variation (%CV) for both assays.

Assay	C0	C2	C3	C4	C5	C5DC	C6	C8	C10	C12	C14	C16	C18
NeoBase	8	8	8	8	8	8	8	8	8	8	8	8	8
Predicate	14	11	10	10	14	17	13	13	13	13	13	10	9

Recovery

Table 5.5: Averaged analyte percent recovery for both assays and associated %CV

	NeoBase Recovery		Predicate Recovery	
Analyte	Average %	%CV	Average %	%CV
ALA	101	8	71	11
ARG	94	7	91	12
CIT	101	7	93	9
GLY	100	9	87	11
LEU	97	9	69	9
MET	89	6	89	18
ORN	91	7	72	14
PHE	99	7	96	22
TYR	101	6	81	11
VAL	90	10	68	16
C0	93	7	139	12

C2	97	6	67	23
C3	100	5	97	19
C4	94	4	104	11
C5	98	6	111	7
C5DC	102	4	102	14
C6	95	4	89	10
C8	97	5	105	21
C10	101	5	83	10
C12	97	5	106	33
C14	95	5	95	18
C16	93	5	98	15
C18	94	6	89	18

Measurable Ranges

Table 5.6: Measurable ranges for both assays and corresponding clinically significant ranges (all in μM/L).

	NeoBase Range		Predicate Range		Clinical Ranges	
Analyte	Lower	Upper	Lower	Upper	Normal	Cutoff
ALA	4.5	4109	4.92	2868.0	67 - 492	975 - 1625
ARG	0.6	3754	0.31	5469.0	0 - 58	180 - 300
CIT	4.8	1711	0.53	2169.2	0 - 36	113 - 188
GLY	50.4	4794	9.81	4023.3	238 - 808	975 - 1625
LEU	1.3	2598	9.06	3078.0	26 - 239	263 - 438

Table 5.6: Measurable ranges for both assays and corresponding clinically significant ranges (all in μM/L). **Continued.**

	NeoBase Range		Predicate Range		Clinical Ranges	
Analyte	Lower	Upper	Lower	Upper	Normal	Cutoff
MET	2.5	1192	8.03	1476.7	3 - 59	120 - 200
ORN	0.6	3825	1.60	4675.4	5 - 214	360 - 600
PHE	0.3	2395	0.75	2906.0	10 - 130	225 - 375
TYR	1.2	2867	1.42	2537.1	14 - 194	578 - 963
VAL	0.6	2388	114.80	2900.0	34 - 213	300 - 500
C0	0.2	2298	2.13	4143.0	6.6 - 70.6	90 - 150
C2	0.2	732	0.13	166.3	6.2 - 44.3	128 - 213
C3	0.03	88	0.09	130.7	0 - 4.9	9.75 - 16.25
C4	0.07	59.61	0.02	58.4	0 - 0.92	2.25 - 3.75
C5	0.04	58.73	0.02	101.6	0 - 0.61	1.88 - 3.13
C5DC	0.08	28.88	0.16	30.9	0 - 0.22	0.6 - 1
C6	0.08	61.50	0.01	38.0	0 - 0.33	0.98 - 1.63
C8	0.02	35.42	0.02	48.0	0 - 0.46	1.2 - 2
C10	0.04	28.69	0.01	46.6	0 - 0.32	1.35 - 2.25
C12	0.04	42.99	0.04	76.4	0 - 0.74	1.88 - 3.13
C14	0.02	41.88	0.01	32.1	0 - 0.55	1.5 - 2.5
C16	0.10	107.40	0.04	76.4	0.08 - 5.78	11.25 - 18.75
C18	0.04	32.19	0.01	55.9	0.1 - 1.69	3 - 5.0

Method Correlation

The method comparison study was executed based on the CLSI EP9-A2 guidelines. Samples were prepared in duplicates and assayed using both the NeoBase and NeoGram kits according to the corresponding kit inserts resulting in total of 158 samples acquired with each method. Each sample was tested twice within the same run within each method. Linear regression analysis provided correlation coefficients (R and R2) as well as slopes (Tables 5.7 to 5.9). The results from this study indicate that the test and predicate method correlated very well.

Table 5.7: Method comparison: Correlation coefficient R and the R^2 for all amino acids.

Analyte	ALA	ARG	CIT	GLY	LEU	MET	ORN	PHE	TYR	VAL
R	0.99	0.99	0.98	0.98	0.98	0.98	0.97	0.99	0.99	0.98
R^2	0.98	0.98	0.95	0.95	0.95	0.97	0.95	0.98	0.99	0.96

Table 5.8: Method comparison: Correlation coefficient R and the R^2 for free carnitine and acylcarnitines.

Analyte	C0	C2	C3	C4	C5	C5DC	C6	C8	C10	C12	C14	C16	C18
R	0.98	0.98	1.00	0.98	0.99	0.97	0.98	0.98	0.98	0.98	0.98	0.99	0.98
R^2	0.95	0.96	1.00	0.97	0.97	0.95	0.96	0.96	0.97	0.97	0.96	0.98	0.97

Table 5.9: Method comparison: Slopes and Intercepts for all amino acids.

Analyte	ALA	ARG	CIT	GLY	LEU	MET	ORN	PHE	TYR	VAL
Slope (B)	1.24	1.02	0.98	1.21	1.04	0.93	1.35	0.90	1.12	1.00
Intercept (A)	165.70	-1.00	1.50	-5.50	34.50	-2.90	-1.90	4.30	-0.40	9.60

Table 5.10: Method comparison: Slopes and Intercepts for free carnitine and acylcarnitines.

Analyte	C0	C2	C3	C4	C5	C5DC	C6	C8	C10	C12	C14	C16	C18
Slope (B)	0.97	1.19	1.05	0.96	0.76	0.89	1.01	0.99	1.16	1.02	0.98	1.03	0.96
Intercept (A)	3.30	-7.70	0.00	0.00	0.00	0.10	0.00	0.00	0.00	0.00	0.00	0.10	0.50

(2) Clinical

CLINICAL CORRELATION STUDIES

The clinical correlation studies took place at two different US newborn screening laboratories that evaluated the NeoBase kit in parallel to the predicate device (identical specimens were analyzed as paired samples by both methods). The sample set consisted of 9416 random neonatal samples, 104 samples from with true positive diagnoses, and 320 artificially enriched dried blood spots. Clinical correlation was established by assessing whether or not the methods were concordant in determining the paired samples to have analyte concentration values above or below their corresponding cutoffs. Examination on the number of

concordant pairs for each analyte (cases in which both methods agreed) provided the percent agreements shown in Table 5.11.

Table 5.11: Percent agreement in clinical determinations by both methods (all samples)

Analyte	Total # of Observations	% Agreement	Analyte	Total # of Observations	% Agreement
ALA*	2559	99.7%	C14#	9813	99.9%
ARG*	2564	100.0%	C16#	9803	99.9%
CIT#	9805	99.8%	C18#	9781	100.0%
GLY*	2474	99.8%	C4-OH/C3DC*	2564	99.5%
LEU#	9771	99.6%	C5:1	9840	100.0%
MET#	9808	99.7%	C5-OH/C4DC*	7276	98.4%
ORN*	2554	99.7%	C6DC	9840	99.1%
PHE#	9749	99.8%	C10:1	9840	100.0%
TYR#	9803	99.9%	C12:1*	2564	100.0%
VAL#	9745	99.5%	C14:1	9840	99.9%
C0#	9461	99.9%	C14:2*	2564	99.9%
C2#	9808	100.0%	C14-OH*	2564	99.9%
C3#	9781	99.9%	C16:1*	2564	100.0%
C4*	2559	99.9%	C16:1-OH	9840	100.0%
C5#	9809	99.6%	C16-OH	9840	100.0%
C5DC	9840	97.2%	C18:1	9840	99.0%
C6	9840	100.0%	C18:1-OH	9840	100.0%
C8	9840	100.0%	C18:2*	2564	99.9%
C10	9840	99.9%	C18-OH	9840	100.0%
C12*	2559	99.9%			

*Only one of the two sites measured the indicated analytes.

#Several observations were associated with plate controls out of range. These observations were removed from the analysis and thus the lesser number of observations vs. the 9840 total.

COMPARISON OF TRUE POSITIVE SAMPLE RESULTS BETWEEN ASSAYS

In addition to the 104 true positive samples analyzed at the newborn screening sites, PerkinElmer R&D analyzed four Tyrosinemia Type I samples in parallel with both methods. Two of the 4 samples were acquired from the same subject approximately 14 days apart. The results for all true positive samples are summarized in Table 5.12

Table 5.12: Summary of the analysis of true Positive samples by the NeoBase and NeoGram assays. Disorders, along with number of corresponding true positive samples analyzed and detected are shown. N=108

Disorder Abbreviation	Disorder Full name	Number Analyzed	Detected by NeoBase Study Cutoffs	Detected by Predicate Study Cutoffs
3MCC	3-Methylcrotonyl-CoA Carboxylase Deficiency	9	9	9
CUD	Carnitine Uptake Defect	10	10	10
CTD	Carnitine Transporter Defect	1	1	1
CPT-1	Carnitine Palmitoyltransferase I Deficiency	1	1	1

GA-1	Glutaric acidemia, type 1	9	9	9
HCY	Homocystinuria	7	7	7
IVA	Isovaleric acidemia	9	9	9
2MBDD	2-Methylbutyryl-CoA Dehydrogenase Deficiency	1	1	1
MCAD	Medium-Chain Acyl-CoA Dehydrogenase Deficiency	16	16	16
MCD	Multiple CoA Carboxylase Deficiency	3	3	3
MMA	Methylmalonic Aciduria	2	2	2
PPA	Propionic Acidemia	3	3	3
MSUD	Maple Syrup Urine Disease	2	2	2
SCAD	Short-Chain Acyl-CoA Dehydrogenase Deficiency	1	1	1
PKU	Phenylketonuria	12	12	12
CPT-2	Carnitine Palmitoyltransferase II Deficiency	**1**	**0**	**0**
LCHAD	Long-Chain 3-hydroxyacyl-CoA Dehydrogenase Deficiency	5	5	5
VLCAD	Very Long-Chain Acyl-CoA Dehydrogenase Deficiency	**11**	**10**	**10**
VLCHAD	Very Long-Chain 3-hydroxyacyl-CoA Dehydrogenase Deficiency	1	1	1
TYR 1	Tyrosinemia Type 1	**4**	**4**	**0**

The data presented in Table 5.12 indicate that with the exception of Tyrosinemia Type 1, the NeoBase assay is just as sensitive as the predicate NeoGram assay in detecting the true positive samples. The two samples that neither of the two assays were able to detect based on the study cutoffs were a CPT-2 and a VLCAD case. The CPT-2 sample had been in storage for over three years and the VLCAD sample had been stored at room temperature for over one year. As a result, it is very likely that the acylcarnitine analytes in these samples had experienced a significant degree of decay during that period of time and thus causing the corresponding analytes to be below the study cutoffs.

One significant difference between the NeoBase and the NeoGram assays is the fact that the NeoBase assay enables the measurement and detection of succinylacetone (SA), the primary marker for Tyrosinemia Type I. The results of the analysis of four Tyrosinemia Type I true positive samples are presented in Table 5.13.

Table 5.13: SA and Tyr results for four true positives Tyrosinemia Type I samples. Results are shown in µM quantities.

Site	Assay	NeoBase		Predicate
	Marker	SA	Tyr	Tyr
Patient 1	Sample1_(25 hours of age)	4.42	66	NA
	Sample2_(15 days of age)	5.73	232	NA
Patient 2	Sample1	4.19	144	135
Patient 3	Sample2	4.46	227	247

From the data presented in Table 5.13 it is evident that when patients are afflicted with Tyrosinemia Type I, their blood contains highly elevated levels of succinylacetone. However, elevated levels of Tyrosine are not always associated with this disorder. In the four cases presented in table 5.13, all four SA measurements are above the corresponding cutoff of >2µM. However, all available Tyrosine measurements are below cutoffs (<300µM). Such striking

results indicate that inclusion of succinylacetone in the panel provides improved specificity and sensitivity in the detection of Tyrosinemia type I.

Finally, the established performance characteristics and method comparison at the analytical and clinical levels show that the Neo Base Non-derivatized MSMS kit is substantial equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

PerkinElmer Inc.
c/o Ms. Kay A. Taylor
Senior Manager Regulatory Affairs
Wallac Oy
8275 Carloway Road
Indianapolis, IN 46236

JUL - 9 2009

Re: k083130
Trade Name: NeoBase Non-Derivatized MSMS Kit
Regulation Number: 21 CFR §862.1055
Regulation Name: Newborn screening test system for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry.
Regulatory Class: Class II
Product Codes: NQL
Dated: June 10, 2009
Received: June 11, 2009

Dear Ms. Taylor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **k083130**

Device Name: **NeoBase Non-derivatized MSMS kit**

Indications For Use:

The NeoBase Non-derivatized MSMS reagent kit is intended for the measurement and evaluation of amino acids, succinylacetone, free carnitine, and acylcarnitine concentrations from newborn heel prick blood samples dried on filter paper.

Quantitative analysis of these analytes (Table 1) and their relationship with each other is intended to provide analyte concentration profiles that may aid in screening newborns for metabolic disorders.

Table 1. Analytes measured by the NeoBase Non-derivatized MSMS Kit.

ANALYTE NAME	ABBREVIATION
Amino acids	
Alanine	Ala
Arginine	Arg
Citrulline	Cit
Glycine	Gly
Leucine/Isoleucine/Hydroxyproline*	Leu/Ile/Pro-OH
Methionine	Met
Ornithine	Orn
Phenylalanine	Phe
Proline	Pro

Prescription Use XX AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Carol C Benson

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Evaluation and Safety

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ANALYTE NAME	ABBREVIATION
Carnitines	
Acetylcarnitine	C2
Propionylcarnitine	C3
Malonylcarnitine / 3-Hydroxy-butyrylcarnitine*	C3DC/C4OH
Butyrylcarnitine	C4
Methylmalonyl / 3-Hydroxy-isovalerylcarnitine*	C4DC/C5OH
Isovalerylcarnitine	C5
Tiglylcarnitine	C5:1
Glutarylcarnitine / 3-Hydroxy-hexanoylcarnitine*	C5DC/C6OH
Hexanoylcarnitine	C6
Adipylcarnitine	C6DC
Octanoylcarnitine	C8
Octenoylcarnitine	C8:1
Decanoylcarnitine	C10
Decenoylcarnitine	C10:1
Decadienoylcarnitine	C10:2
Dodecanoylcarnitine	C12
Dodecenoylcarnitine	C12:1
Tetradecanoylcarnitine (Myristoylcarnitine)	C14
Tetradecenoylcarnitine	C14:1
Tetradecadienoylcarnitine	C14:2
3-Hydroxy-tetradecanoylcarnitine	C14OH
Hexadecanoylcarnitine (palmitoylcarnitine)	C16
Hexadecenoylcarnitine	C16:1
3-Hydroxy-hexadecanoylcarnitine	C16OH
3-Hydroxy-hexadecenoylcarnitine	C16:1OH
Octadecanoylcarnitine (Stearoylcarnitine)	C18
Octadecenoylcarnitine (Oleylcarnitine)	C18:1
Octadecadienoylcarnitine (Linoleylcarnitine)	C18:2
3-Hydroxy-octadecanoylcarnitine	C18OH
3-Hydroxy-octadecenoylcarnitine	C18:1OH
Ketones	
Succinylacetone	SA

*Analytes in these rows are either isomers or isobars and cannot be distinguished in the tandem mass spectrometry experiment.

Prescription Use __XX__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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